IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of: MARSH et al.	
Application No.: 10/728,547	Group Art Unit: 3767
Filed: December 5, 2003	Examiner: Gray, Phillip
For: VARIABLE EXTENSION COMBINED SPINAL/EPIDURAL NEEDLE SET AND METHOD FOR ITS USE	Confirmation No.: 8789

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Sir:

Further to the Notice of Appeal filed on February 5, 2009, for the subject application, a brief in support of the appeal is now submitted. Submission of a brief in support of the appeal in this case is due by April 5, 2009. Accordingly, this brief is being timely filed.

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REAL PARTY IN INTEREST

The real party in interest is BECTON, DICKINSON AND COMPANY, the assignee of the instant application.

RELATED APPEALS AND INTERFERENCES

The undersigned is not aware of any appeals or interferences that are related to this appeal, or which will affect or have a bearing on this appeal.

STATUS OF CLAIMS

Claims 1-20 were finally rejected in an Office Action mailed on December 11, 2008 ("the Final Office Action"), and are the subject of this appeal.

STATUS OF AMENDMENTS

No claims have been amended, added or cancelled subsequent to the Final Office Action.

SUMMARY OF CLAIMED SUBJECT MATTER

The claimed subject matter encompasses an epidural needle. Independent claim 1 is directed to an epidural needle comprising:

> a stiff elongate tube (16) defining a longitudinal axis having a proximal end (18), a distal end (20) and an axial hollow bore (12) having an inside diameter therethrough, wherein the distal end is a sharpened tip and the tube has sufficient stiffness to penetrate a patient's tissue and to be placed in a patient's epidural space; *(pages 6-7, paragraph 0026; page 10, paragraph 0035)*
>
> a hub (22) having a proximal end (24), a distal end (26) and an open passageway therethrough (28), said hub being attached to the proximal end of said elongate tube so that said hollow bore of said elongate tube is in fluid communication and substantial axial alignment with said open passageway, said hub further having a cavity (30) therein disposed between said proximal end and said distal end of said hub; *(pages 6-7, paragraph 0026)*
>
> a resilient member (32) permanently mounted within the hub having an opening therethrough (34) defining an inner diameter and disposed in said cavity so that said opening is substantially axially aligned and in

fluid communication with said open passageway; *(pages 6-7, paragraph 0026)* and

a clamp (36) selectively movable between an open position wherein said inner diameter of said resilient member is substantially unaffected and a clamp position wherein said clamp causes a strain to at least a portion of said resilient member thereby reducing, but not occluding, said inner diameter of said opening through at least a portion of said resilient member. *(page 7, paragraph 0027; Figures 5A-5B, 9 and 10)*

Independent claim 10 is directed to a combined spinal epidural needle set comprising:

an epidural needle (10) including stiff elongate tube (16) defining a longitudinal axis having a proximal end (18), a distal end (20) and an axial hollow bore (12) having an inside diameter therethrough, wherein the distal end is a sharpened tip suitable for penetrating a patient's tissue and entry of the patient's epidural space, *(pages 6-7, paragraph 0026; page 10, paragraph 0035)*

said epidural needle having a hub (22) having a proximal end (24), a distal end (26) and an open passageway therethrough (28), said hub being attached to the proximal end of said elongate tube so that said hollow

bore of said elongate tube is in fluid communication and substantial axial alignment with said open passageway and wherein said hub further having a cavity (30) disposed between said proximal end and said distal end of said hub, *(pages 6-7, paragraph 0026)*

a resilient member (32) having an opening therethrough (34) defining an inner diameter and disposed in said cavity so that said opening is substantially axially aligned and in fluid communication with said open passageway, *(pages 6-7, paragraph 0026)*

and a clamp (36) having a releasable latch (38) disposed about said resilient member, said clamp being selectively movable between an open position wherein said inner diameter of said resilient member is substantially unaffected and a clamp position wherein said clamp causes a strain to said resilient member thereby reducing said inner diameter of said opening through said resilient member; *(page 7, paragraphs 0027- 0028; Figures 5A-5B, 9 and 10)* and

a spinal needle (14) having an outside diameter less than said inside diameter of said hollow tube disposed within said hollow bore, and wherein a practitioner using said epidural needle to position said spinal needle may

freely axially move said spinal needle within said hollow bore with respect to said epidural needle and fix a position of said spinal needle relative to said epidural needle by said reduction of said inner diameter opening through said resilient member to a diameter less than said outside diameter of the spinal needle by movement of said clamp to said clamp position thereby to grasp releasably the spinal needle sufficiently to fix the position of the spinal needle with respect to the epidural needle, wherein the spinal needle is not occluded in the clamp position, thereby permitting delivery of medicament to a patient's subarachnoid space. *(page 8, paragraph 0029; Figures 6-7)*

Independent claim 19 is directed to an epidural needle comprising:

a stiff elongate tube (16) defining a longitudinal axis having a proximal end (18), a distal end (20) and an axial bore (12) having an inside diameter therethrough, wherein the distal end is a sharpened tip and the tube has sufficient stiffness to penetrate a patient's tissue and to permit entry into a patient's epidural space; *(pages 6-7, paragraph 0026; page 10, paragraph 0035)*

a hub (22) having a proximal end (24), a distal end (26) and an open passageway therethrough (28), the hub being attached to the elongate tube so that the hollow bore

of the elongate tube is in fluid communication and substantial axial alignment with the open passageway, the hub further having a cavity (30) disposed therein between the proximal end and the distal end of the hub; *(pages 6-7, paragraph 0026)*

a resilient member (32), distinct from the elongate tube, having an opening (34), at least in part, therethrough defining an inner diameter and disposed in the cavity so that the opening is substantially aligned and in fluid communication with the open passageway, wherein the resilient member fixedly secured within the cavity and restrained from axial displacement with respect to the hub; *(pages 6-7, paragraph 0026)* and

a clamp (36) selectively moveable between a first position wherein the resilient member is undeformed and a second position wherein the resilient member is deformed such that the inner diameter of the opening is changed through at least a portion of the resilient member, but the inner diameter of the opening is not occluded. *(page 7, paragraph 0027; Figures 5A-5B, 9 and 10)*

The dependent claims are directed to various embodiments of the disclosed epidural needle.

A copy of the appealed claims is appended hereto, beginning at page 32.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Whether claims 1, 10 and 19 are anticipated under 35 U.S.C. § 102(b) by Chu et al (US 5,397,310; "Chu").

II. Whether claims 1-20 are unpatentable under 35 U.S.C. § 103(a) over McWha et al. (US 5,480,389; "McWha") in view of Schaffer (US 5,429,616; "Schaffer").

ARGUMENT

I. Rejection of Claims 1, 10 and 19 Under 35 U.S.C. § 102

Claims 1, 10 and 19 stand finally rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Chu. The Examiner states in the Final Office Action that Chu discloses a catheter introducer sheath assembly and discloses a needle (as shown in Figures 11-15) comprising an elongate tube (120) with sharpened tip, a hub (near 2a or 4 as in Figure 3) and a resilient member (22 shown in Figure 3) and a clamp (12/24 as in Figure 3), and where the clamp is in an open position (4 or 4b) and a clamp position (shown in Figure 4a) wherein "the clamp causes a strain to at least a portion of the resilient member thereby reducing but not occluding, the inner diameter of the opening through at least a portion of the resilient member," and further discloses a spinal needle (124) whereby the spinal needle may become fixed but not occluded (see Figure 11A).

According to the Examiner, the elongate tube 120 of Chu is "stiff" and "has a sufficient stiffness to penetrate a patient's tissue and be placed in a patient's epidural space." The Examiner believes that the elongate tube of Chu appears to hold its shape and is not flexible (see Figure 11) and would be fully capable of piercing tissue (see Figures 6-6E) and be placed in a epidural space or permit delivery to a patient's subarachnoid space (see column 1, lines 60-67).

The Examiner takes the position that the ability to "penetrate a patient's tissue and be placed in a patient's epidural space" is a functional limitation. The Examiner states that it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art

reference disclosing the structural limitations of the claim, and that where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function.

Appellants maintain that Chu does not anticipate the subject matter of claims 1, 10 and 19. It has long been the law that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 631, 638 (Fed. Cir. 1987). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). In addition, for an anticipation rejection to be proper, the reference must clearly and unequivocally disclose the claimed subject matter or direct those skilled in the art to the claimed subject matter without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *See In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008) ("But disclosure of each element is not quite enough – this court has long held that '[a]nticipation requires the presence in a single prior art disclosure of all elements of

a claimed invention *arranged as in the claim.*'") (quoting *Connell v. Sears, Roebuck & Co.,* 722 F.2d 1542, 1548 (Fed. Cir. 1983) (emphasis in original).

Each of the claims 1, 10 and 19 is directed to, *inter alia*, an ***epidural needle***. This is explicitly recited in the body of claim 10 ("A combined spinal epidural needle set comprising: an ***epidural needle*** . . . .") (emphasis added). Nowhere does Chu disclose an epidural needle. Indeed, Chu does not use the term "epidural" at all, and the only use of the term "needle" is in relation to an introducer needle for introduction of a guidewire into an artery. *See* col. 9, lines 7-13. Although the Examiner asserts that Figures 11-15 of Chu show a needle, these figures actually show flexible sheath 120 surrounding either dilator 122 or catheter 124. Clearly, none of these elements can be considered a needle. Furthermore, since catheter 124 is not a needle, it cannot read on the "spinal needle" recitation in claim 10, as asserted by the Examiner. *See Verdegaal*, 814 F.2d at 638. Accordingly, Chu cannot anticipate claim 10.

Similarly, claims 1 and 19 also are directed to an "epidural needle." Although the term appears only in the preamble, Appellants maintain that the term "epidural needle" constitutes a positive limitation of the invention recited in claims 1 and 19, and, as such, must be given patentable weight. "The effect preamble language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Here, the title of the invention refers to an "epidural needle," *see* page 1, line 5, the background describes problems with prior art "epidural needles," *see* page 3, lines 10-31, the summary describes the present invention as being an "epidural needle," *see* page 4, line 1

t0 page 5, line 11, and the detailed description provides preferred embodiments of the inventive "epidural needle," *see* page 6, line 21 to page 13, line 17.

Thus, the specification makes clear that term "epidural needle" does not merely state a purpose or intended use for the claimed structure, but rather is a positive limitation of claims 1 and 19 that must be given patentable weight. *See id.* ("[T]he '915 specification makes clear that the inventors were working on the particular problem of an effective optical communication system not on general improvements in conventional optical fibers. To read the claim in light of the specification indiscriminately to cover all types of optical fibers would be divorced from reality."). Viewed in this light, it is simply irrelevant whether, as the Examiner alleges, the elongate tube of Chu could inherently penetrate a patient's tissue for placement in the epidural space. *See id.* ("Viewed in this manner, the fact that the '101 luminescent fiber could inherently transmit information for a few meters becomes irrelevant. The '101 patent does not disclose all the limitations of the claimed 'optical waveguide' as that term is structurally defined by the '915 inventors."). Because, as discussed above with respect to claim 10, Chu does not disclose an epidural needle, it cannot anticipate claims 1 and 19 as well.

However, even if the term "epidural needle" in claims 1 and 19 was not treated as a positive limitation (which Appellants maintain would constitute reversible error), Appellants maintain that the Examiner has not met his burden of establishing that the elongate tube of Chu could inherently penetrate a patient's tissue for placement in the epidural space. According to the Examiner, Figure 11 shows that the elongate tube of Chu appears to hold its shape and is not flexible, while Figures 6-6E show that the elongate tube would be fully capable of piercing tissue and being placed in a epidural

space or permitting delivery to a patient's subarachnoid space." However, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic ***necessarily*** flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Here, the Examiner has not provided any facts or technical reasoning to support the conclusion that the elongate tube in Chu is of sufficient stiffness to penetrate a patient's tissue and to be placed in a patient's epidural space. The Examiner has merely stated that it "appears" to be the case. "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *Robertson*, 169 F.3d at 745 (citations omitted).

Indeed, to the contrary, the figures in Chu relied upon by the Examiner themselves strongly support the conclusion that the elongate tube does not have the requisite stiffness. Tube 120 in Figure 11 appears stiff only because it surrounds dilator 122. Indeed, tube 120 is described as "flexible," as is dilator 122. *See* col. 10, line 61 to col. 11, line 2. Furthermore, both dilator 122 and tube 120 are shown passing over guidewire 52a, which strongly suggests that the tube 120 lacks sufficient stiffness to penetrate a patient's tissue. This is more clearly shown in Figures 6-6E, where catheter tube 8 is shown as flexing along its length. According to Chu, guidewire 52 is positioned in an arterial passageway using an introducer needle using the Seldinger method. Angiographic catheter 8 is then threaded over the guidewire such that it is positioned in the artery. *See* col. 9, lines 7-16. The need for an introducer needle and guidewire is consistent with the conventional use of a ***flexible*** catheter tube for cardiac catheterization

and compels the conclusion that the elongate catheter tube in Chu is not sufficiently stiff to penetrate a patient's tissue and to be placed in a patient's epidural space.

In addition, Appellants maintain that Chu also fails to disclose a clamp for reducing, but not occluding, the inner diameter of a resilient member, as required in claims 1, 10 and 19. As explained in Appellants' previous submission, Chu is directed to "an improved device for ***closure*** of a throughpassage for use, for example, as a valve for a catheter or as a gripping member for a device such as a guidewire placed in the through-passage or channel" (emphasis added). *See* col. 1, lines 59-63. This closure device "prevent[s] backflow of blood or other fluid from the proximal end of the catheter." *See* col. 1, lines 19-21. As shown in Figures 2-2C, the closure device comprises distal body member 4 and proximal body member 12. Counter-clockwise rotation of proximal body member 12 relative to distal body member 4 causes compression member 24 to move radially inward to compress tube member 22 to "***close the opening of the through-passage***." *See* col. 5, lines 39-47. Thus, in direct contrast to the claimed invention, Chu teaches occluding the opening of the tubing member.

The Examiner maintains in the Final Office Action that Figure 4A of Chu discloses the clamp causing a strain to at least a portion of the resilient member thereby reducing, but not occluding, the inner diameter of the opening. Although Figure 4A does indeed appear to show the partial compression of tube member 22, the Examiner fails to note that Figure 4A is directed to the ***assembly*** of the closure device. *See* col. 7, lines 27-28. As shown in Figure 4B, compression member 24 is gradually progressively compressed against tube member 22 until the maximum is reached, at which state it remains until sufficient further rotation causes the abrupt transition and surface portion 28

of the cam surface to register with the compression member and permit spring outwardly of the compression member to permit repetition of the rotational motion. *See* col. 8, lines 38-49. Figures 4C-G show various positions of the cam surface relative to the compression member during the assembly stages, with Figure 4G showing the uncompressed state of tube member 22 following assembly. *See* col. 8, lines 49-51. Critically, Chu states that once the device is assembled, it cannot be disassembled by rotation in either direction. *See* col. 8, lines 51-54.

Thus, the Examiner has provided no evidence that, once assembled, the closure device of Chu is capable of reducing, but not occluding, the inner diameter of tuber member 22. *See Robertson*, 169 F.3d at 745 ("Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'") (citations omitted). Indeed, Chu immediately goes on to state that "[t]he conformable interior of the resilient tubing provides a seal about an object, such as a guidewire, if present in the through-passage when the device is in the closed position." *See* col. 8, lines 65-68. This is consistent with the conclusion that the closure device of Chu is not capable of reducing, ***but not occluding***, the inner diameter of a resilient member, as required in claims 1, 10 and 19.

For the aforementioned reasons, Appellants maintain the claims 1, 10 and 19 are not anticipated by Chu, and respectfully request that the rejection be reversed.

II. Rejection of Claims 1-20 Under 35 U.S.C. § 103

Claims 1-20 stand finally rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over McWha in view of Schaffer. The Examiner states in the Final Office Action that McWha discloses a spinal epidural needle set (Figure 3) comprising an

elongate tube (14) with a sharpened distal end (15), an attached hub (22, 26, 34, 51, 40) and a spinal needle (12) and indicia for location (34). According to the Examiner, the epidural and spinal needle system is fully capable of performing all the associated functional language and claim limitations. The Examiner also states that Schaffer discloses a hub/needle/catheter (see Figures 2 and 5) with a resilient member (50) permanently mounted within a hub (26), and a deformable U-shaped clamp with living hinge (24) with a releasable latch push tab (60) and support arms, which is oriented for perpendicular movement to the elongate tube. Further, the resilient member defines a radiused portion, and the radiused portion of the pair of legs (48) has a radius substantially the same as the radiused portion of the resilient member, as well as a second radiused portion (Figures 3-6). According to the Examiner, the resilient member and clamp of Schaffer are fully capable of performing all the associated functional language and claim limitations.

The Examiner acknowledges that McWha does not disclose a resilient member and a clamp, but asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the epidural needle system as taught by McWha with the resilient member and clamp as taught by Schaffer, since such a modification would provide the epidermal needle system with the resilient member and clamp for providing inward collapsing of the side wall portion to reduce but not occlude the apparatus. According to the Examiner, the resilient member and clamp of Schaffer would be fully capable and known to one of ordinary skill in the art to reduce but not occlude the inner diameter of the opening, as evidenced in Figures 3-6 of Schaffer. Alternatively, the Examiner asserts that it would have been obvious to one having

ordinary skill in the art at the time the invention was made to have the clamp reduce the inner diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (citing *In re Aller,* 105 USPQ 233 (CCPA 1955). In this case, according to the Examiner, it would be obvious for a person having ordinary skill in the art at the time of the invention to modify the range of the clamp (how closed it becomes or how much it reduces the inner diameter) in order to limit the amount of fluid flow through an inner diameter or reduce the space to secure the clamp to another body.

Appellants maintain that the combination of McWha and Schaffer would not have suggested the claimed invention to one of ordinary skill in the art. In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), *viz.*, (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981, 985 (CCPA 1974). Furthermore, although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v.*

Teleflex Inc., 127 S. Ct. 1727, 1741 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

Claims 1-20 Generally

As the Examiner correctly acknowledges, McWha discloses an epidural needle system but does not disclose a resilient member and a clamp. Contrary to the Examiner's assertion, however, one of ordinary skill in the art would not have sought to the epidural needle system of McWha with the resilient member and clamp of Schaffer, nor would such a combination provide an epidural needle comprising a clamp for reducing, but not occluding, the inner diameter of a resilient member, as required by the claims on appeal. Schaffer, entitled "***Occludable Catheter***," discloses just that. According to Schaffer, Figures 1-2 show occludable catheter apparatus 10 "which ***blocks*** the escape of blood when the insertion needle assembly 12, including a needle 14 and a needle hub 16, is removed." *See* col. 4, lines 20-23 (emphasis added). Occludable catheter apparatus 10 includes catheter hub 24 which contains resilient sealing member 50 and a clamp comprising locking members 44 and 46. *See* col. 4, lines 43-46. Sealing member 50 has an axially oriented hole 52 for creating fluid communication between distal end 34 and proximal end 32 of catheter hub 24 until member 50 is compressed by locking members 44 and 46. *See* col. 4, lines 46-49.

Contrary to the Examiner's assertion, Figures 3-6 of Schaffer do not show that the clamp has a range of operation, including an intermediary position of a reduced, but not occluded, state. Figures 3, 5 and 6 clearly show member 50 in the fully dilated state, while Figure 4 clearly shows member 50 in the occluded state. There is no suggestion in

Schaffer that member 50 exists in anything but these two states. *See Robertson*, 169 F.3d at 745 ("Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'") (citations omitted). Indeed, partial occlusion would be contrary to the purpose of the occludable catheter, which is to either allow fluid through or ***completely prevent*** the passage of fluid. *See* col. 1, lines 32-35. In fact, Figure 5 shows locking members 44 and 46 with latch means 60 for maintaining member 50 in the fully occluded position. *See* col. 1, lines 35-38. As such, the references relied upon by the Examiner fail to teach or suggest all the limitations of the appealed claims. *See CFMT, Inc. v. YieldUp Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) ("[O]bviousness requires a suggestion of all limitations in a claim.") (citing *Royka*, 490 F.2d at 985).

The Examiner's reliance on *Aller* does not change this conclusion. Relying on *Aller*, the Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the clamp reduce the inner diameter, since where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. However, subsequent cases shed doubt on the use of *Aller* in this type of rejection. For example, in *In re Yates*, 663 F.2d 1054 (CCPA 1981), as in the instant case, the Examiner cited *Aller* for the proposition that "it is not inventive to discover optimum or workable ranges by routine experimentation." The court, in reversing the rejection, stated that "[t]he problem . . . with such 'rules of patentability' (and the ever-lengthening list of exceptions which they engender) is that they tend to becloud the ultimate legal issue – obviousness – and exalt the formal exercise of squeezing new factual situations into preestablished

pigeonholes. Additionally, the emphasis upon routine experimentation is contrary to the last sentence of section 103." *Id.* at 1056 n.4.

Here, as in *Yates*, the Examiner has exalted form over substance. In relying on *Aller*, the Examiner has failed to provide a rational basis for why one of skill in the art would have modified the clamp in Schaffer as alleged. *See KSR*, 127 S. Ct. at 1741 ("'[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'") (quoting *Kahn*, 441 F.3d at 988). As noted above, partial occlusion of the resilient member if Schaffer would be contrary to the purpose of the occludable catheter, which is to either allow fluid through or completely prevent the passage of fluid. Here, the Examiner's reliance on the so-called "rule of patentability" announced in *Aller* amounts to nothing more than an unsubstantiated allegation of obviousness, which cannot stand in the face of the evidence to the contrary. *See Yates*, 663 F.2d at 1057 ("[M]ere allegations of obviousness are not enough.").

Furthermore, the Examiner has failed to adequately explain why one of skill in the art would have sought to modify the epidural needle of McWha with the resilient member and clamp of Schaffer in the manner asserted. *See KSR*, 127 S. Ct. at 1741 ("[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."). As shown in Figure 2, the epidural needle of McWha is provided with regulating device 10 for adjusting the extension length of spinal needle 12 relative to epidural needle 14 during a combined spinal-epidural ("CSE") technique. *See* col. 5, lines 57-61. Regulating device 10 includes a first sliding member such as an outer cylinder or tube 51 disposed in

sliding relation to a second sliding member such as an inner cylinder or tube 32, each of which are respectively fixed to one of spinal needle 12 or epidural needle 14. *See* col. 6, lines 59-64. In use, after epidural needle 14 has been properly positioned in the epidural space, a finger tab 54 is activated (depressed) by the practitioner, thereby permitting outer tube 51 to be axially slidable in the distal direction with respect to inner tube 32. Inner tube 32, itself fixed to the epidural needle 14, will remain fixed relative to the patient. By continuing to slide the tube 51 distally axially forward, spinal needle 12 will be extended through epidural needle 14 so as to puncture the dura mater and come to rest in the subarachnoid space 104. Upon selecting the appropriate position, the practitioner deactivates (release pressure against) finger tab 54 to lock the position of outer tube 51 relative to inner tube 32. *See* col., 11, lines 14-58.

According to McWha, regulating device 10 allows practitioner to accurately achieve spinal needle extensions while providing smooth, steady sliding action and, hence, valuable tactile feedback. *See* col. 12, lines 1-10. Thus, even assuming *arguendo* that the clamp in Schaffer was capable of reducing, but not occluding, the inner diameter of the resilient member (which Appellants maintain is not the case), common sense clearly dictates that one skilled in the art would not have reasonably looked to combine Schaffer and McWha in the manner asserted by the Examiner. *See KSR*, 127 S. Ct. at 142-43 ("Rigid preventative rules that deny fact finders recourse to common sense . . . are neither necessary under our case law nor consistent with it."). Clearly, there is no benefit to adding a resilient member and clamp, such as disclosed in Schaffer, to the epidural needle disclosed in McWha, which ***already*** provides a mechanism regulating the extension of a spinal needle. *See Ex parte Rinkevich*, Appeal No. 2007-1317 (BPAI

2007) ("In the instant case, we conclude that a person of ordinary skill in the art *having common sense* at the time of the invention would not have reasonably looked to Wu to solve a problem already solved by Savill. Therefore, we agree with Appellants that the Examiner has impermissibly used the instant claims as a guide or roadmap in formulating the rejection."); *Ex parte Green*, Appeal No. 2007-1271 (BPAI 2007) ("Here, we agree with Appellant that a person of ordinary skill in the art would not have reasonably looked to Somashekar to provide a server capability that was already provided by Kuwata. In the record before us, we find only the language of the instant claims suggest such a combination . . . . Therefore, we conclude that an artisan *having common sense* at the time of the invention would not have reasonably considered embedding a server within an existing server in the manner suggested by the Examiner.").

Appellants submit that the Examiner's § 103 rejection rests on nothing more than impermissible hindsight. The Examiner has done nothing more than arguably identify several limitations of the appealed claims separately in the prior art. However, it is only Appellants in their specification that teach positioning a spinal needle with an epidural needle through compressive reduction of the inner diameter of a resilient member. Indeed, Appellants' use of ***compressive*** force to fix the spinal needle relative to the epidural needle is completely contrary to the mechanism employed by McWha, namely the use of tubular members in ***sliding*** relation to one another.

The Federal Circuit has explicitly cautioned against the type of reasoning undertaken by the Examiner in this case. For example, the court in *Ruiz v. A.B. Chance Co.* stated:

> The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an

> obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result - often the very definition of invention. Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole. This court has provided further assurance of an "as a whole" assessment of the invention under § 103 by requiring a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner.

357 F.3d 1270, 1275 (Fed. Cir. 2004).

In the instant case, and as cautioned against by *Ruiz*, the Examiner has used Appellants' disclosure as a roadmap to identify unrelated elements in the cited references to arrive at the claimed invention, when none of the references even remotely suggest the use of compressive force to fix a spinal needle relative to an epidural needle. This is the epitome of "impermissible hindsight," and cannot support a *prima facie* case of obviousness. *See W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1443 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.").

For the aforementioned reasons, Appellants maintain the claims 1-20 are not unpatentable over McWha in view of Schaffer, and respectfully request that the rejection be reversed.

Claims 4 and 13

Claims 4 and 13 ultimately depend from claims 1 and 10, respectively, and specify that the clamp includes a push tab extending away from a releasable latch to facilitate unclamping of the clamp. This is shown in Figure 9 as element 138. The Examiner has failed to provide any evidence that the cited references teach or suggest such a push tab. Indeed, Figure 5 of Schaffer clearly shows that latch 60 lacks a push tab. *See CFMT*, 349 F.3d at 1342 ("[O]bviousness requires a suggestion of all limitations in a claim.") (citing *Royka*, 490 F.2d at 985).

Accordingly, Appellants submit that claims 4 and 13 are not unpatentable over McWha in view of Schaffer independent of the reasons given above for claims 1-20 generally, and respectfully request that the rejection be reversed.

Claims 5 and 14

Claims 5 and 14 depend from claims 4 and 13, respectively, and specify that the push tab is oriented for movement perpendicular to the elongate tube. This again is shown in Figure 9 as element 138. Since there is no longitudinal movement to this motion, the push tab does not affect the relative longitudinal relationship between the epidural needle and the spinal needle. *See* page 8, lines 1-3. As noted above, the Examiner has failed to provide any evidence that the cited references teach or suggest such a push tab, let alone one oriented for movement perpendicular to the elongate tube. Again, Figure 5 of Schaffer clearly shows that latch 60 lacks a push tab. *See CFMT*, 349 F.3d at 1342 ("[O]bviousness requires a suggestion of all limitations in a claim.") (citing *Royka*, 490 F.2d at 985). Furthermore, the mode of action of the latch in Schaffer would

require ***further*** compression to release the latch, which is contrary to the need to prevent occlusion of the fluid pathway of an epidural needle.

Accordingly, Appellants submit that claims 5 and 14 are not unpatentable over McWha in view of Schaffer independent of the reasons given above for claims 1-20 generally, and respectfully request that the rejection be reversed.

Claims 6 and 15

Claims 6 and 15 depend from claims 3 and 14, respectively, and specify that the clamp includes a support leg that limits movement of the latch. This is shown in Figure 9 as element 139. The support leg prevents the push tab from breaking the latch if excessive force is applied downwardly. *See* page 8, lines 3-6. The Examiner has failed to provide any evidence that the cited references teach or suggest such a support leg. *See CFMT*, 349 F.3d at 1342 ("[O]bviousness requires a suggestion of all limitations in a claim.") (citing *Royka*, 490 F.2d at 985). Indeed, Figure 5 of Schaffer clearly shows that latch 60 lacks a support leg.

Accordingly, Appellants submit that claims 6 and 15 are not unpatentable over McWha in view of Schaffer independent of the reasons given above for claims 1-20 generally, and respectfully request that the rejection be reversed.

Claim 11

Claim 11 depends from claim 10 and specifies that the spinal needle includes indicia for providing an indication of the location of the spinal needle with respect to the epidural needle. Although the Examiner is correct that the spinal/epidural needle set in McWha is provided with indicia, the indicia, as shown in Figure 3, are located on the outside surface of inner tube 32, to which the ***epidural needle*** is affixed. *See* col. 8, lines

1-4. The Examiner has pointed to nothing in McWha that suggests that the spinal needle should be marked with indicia, as required by claim 11. *See CFMT*, 349 F.3d at 1342 ("[O]bviousness requires a suggestion of all limitations in a claim.") (citing *Royka*, 490 F.2d at 985).

Accordingly, Appellants submit that claim 11 is not unpatentable over McWha in view of Schaffer independent of the reasons given above for claims 1-20 generally, and respectfully request that the rejection be reversed.

CONCLUSION

For the foregoing reasons, Applicants maintain that claims 1-20 meet the requirements for patentability under 35 U.S.C. §§ 102 and 103. Accordingly, reversal of the Examiner's rejections is appropriate and is respectfully solicited.

Respectfully submitted,

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CLAIMS APPENDIX

1. An epidural needle, comprising:

A stiff elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial hollow bore having an inside diameter therethrough, wherein the distal end is a sharpened tip and the tube has sufficient stiffness to penetrate a patient's tissue and to be placed in a patient's epidural space;

a hub having a proximal end, a distal end and an open passageway therethrough, said hub being attached to the proximal end of said elongate tube so that said hollow bore of said elongate tube is in fluid communication and substantial axial alignment with said open passageway, said hub further having a cavity therein disposed between said proximal end and said distal end of said hub;

a resilient member permanently mounted within the hub having an opening therethrough defining an inner diameter and disposed in said cavity so that said opening is substantially axially aligned and in fluid communication with said open passageway; and

a clamp selectively movable between an open position wherein said inner diameter of said resilient member is substantially unaffected and a clamp position wherein said clamp causes a strain to at least a portion of said resilient member thereby reducing, but not occluding, said inner diameter of said opening through at least a portion of said resilient member.

2. The epidural needle of claim 1 wherein at least a portion of said clamp is disposed within the hub and a portion of the clamp projects outwardly from said hub to facilitate

the practitioner's selective movement of said clamp between said open position and said clamp position.

3. The epidural needle of claim 2 wherein said portion of said clamp that projects outwardly from said hub further includes a releasable latch for selectively retaining said clamp in said clamp position.

4. The epidural needle of claim 3 further include a push tab extending away from the releasable latch to facilitate unclamping said clamp from said clamp position.

5. The epidural needle of claim 4 wherein the push tab is oriented for movement perpendicular to the elongate tube.

6. The epidural needle of claim 3 further including a support leg that limits movement of the latch.

7. The epidural needle of claim 1 wherein the clamp includes a pair of legs defining at least one radiused portion therein.

8. The epidural needle of claim 7 wherein the resilient member defines a radiused portion and the radiused portion of the pair of legs has a radius substantially the same as the radiused portion of the resilient member.

9. The epidural needle of claim 8 where the pair of legs defines a second radiused portion adjacent to the at least one radiused portion.

10. A combined spinal epidural needle set comprising:

an epidural needle including stiff elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial hollow bore having an inside diameter therethrough, wherein the distal end is a sharpened tip suitable for penetrating a patient's tissue and entry of the patient's epidural space, said epidural needle having a hub having a proximal end, a distal end and an open passageway therethrough, said hub being attached to the proximal end of said elongate tube so that said hollow bore of said elongate tube is in fluid communication and substantial axial alignment with said open passageway and wherein said hub further having a cavity disposed between said proximal end and said distal end of said hub, a resilient member having an opening therethrough defining an inner diameter and disposed in said cavity so that said opening is substantially axially aligned and in fluid communication with said open passageway, and a clamp having a releasable latch disposed about said resilient member, said clamp being selectively movable between an open position wherein said inner diameter of said resilient member is substantially unaffected and a clamp position wherein said clamp causes a strain to said resilient member thereby reducing said inner diameter of said opening through said resilient member; and

a spinal needle having an outside diameter less than said inside diameter of said hollow tube disposed within said hollow bore, and wherein a practitioner using said epidural needle to position said spinal needle may freely axially move said spinal needle

within said hollow bore with respect to said epidural needle and fix a position of said spinal needle relative to said epidural needle by said reduction of said inner diameter opening through said resilient member to a diameter less than said outside diameter of the spinal needle by movement of said clamp to said clamp position thereby to grasp releasably the spinal needle sufficiently to fix the position of the spinal needle with respect to the epidural needle, wherein the spinal needle is not occluded in the clamp position, thereby permitting delivery of medicament to a patient's subarachnoid space.

11. The combined spinal epidural needle set of claim 10 wherein the spinal needle includes an indicia formed thereon for providing an indication to the practitioner of the location of the spinal needle with respect to the epidural needle.

12. The combined spinal epidural needle set of claim 11 wherein at least a portion of said clamp projects outwardly from said hub to facilitate the practitioner's selective movement of said clamp between said open position and said clamp position.

13. The combined spinal epidural needle set of claim 12 further including a push tab extending away from the releasable latch to facilitate unclamping said clamp from said clamp position.

14. The combined spinal epidural needle set of claim 13 wherein the push tab is oriented for movement perpendicular to the elongate tube.

15. The combined spinal epidural needle set of claim 14 further including a support leg that limits movement of the latch.

16. The combined spinal epidural needle set of claim 10 wherein the clamp includes a pair of legs defining at least one radiused portion therein.

17. The combined spinal epidural needle set of claim 16 wherein the resilient member defines a radiused portion and the radiused portion of the pair of legs has a radius substantially the same as the radiused portion of the resilient member.

18. The combined spinal epidural needle set of claim 17 where the pair of legs defines a second radiused portion adjacent to the at least one radiused portion.

19. An epidural needle including:

a stiff elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial bore having an inside diameter therethrough, wherein the distal end is a sharpened tip and the tube has sufficient stiffness to penetrate a patient's tissue and to permit entry into a patient's epidural space;

a hub having a proximal end, a distal end and an open passageway therethrough, the hub being attached to the elongate tube so that the hollow bore of the elongate tube is in fluid communication and substantial axial alignment with the open passageway, the hub further having a cavity disposed therein between the proximal end and the distal end of the hub;

a resilient member, distinct from the elongate tube, having an opening, at least in part, therethrough defining an inner diameter and disposed in the cavity so that the opening is substantially aligned and in fluid communication with the open passageway, wherein the resilient member fixedly secured within the cavity and restrained from axial displacement with respect to the hub; and

a clamp selectively moveable between a first position wherein the resilient member is undeformed and a second position wherein the resilient member is deformed such that the inner diameter of the opening is changed through at least a portion of the resilient member, but the inner diameter of the opening is not occluded.

20. The needle of claim 19 wherein the clamp comprises a deformable U-shaped member having an apex and two legs, wherein a living hinge is disposed at the apex and a latch is disposed on the legs for securing the legs in a relatively fixed position.

EVIDENCE APPENDIX

None.

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RELATED PROCEEDINGS APPENDIX

None.